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PhRMA

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: Draft Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products; Docket No. 98N-1265

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing over $24 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures. PhRMA is pleased to submit these comments on FDA's draft Memorandum of Understanding (MOU) on interstate distribution of compounded drug products.

Investigation of Complaints: The draft MOU specifies that the State Board of Pharmacy and the State Medical Licensing Board should investigate complaints involving compounding by pharmacists or physicians, respectively. PhRMA agrees that the MOU needs to be very clear about what state agencies have responsibility for investigating complaints arising out of the compounding of prescription drugs, and that the state agencies need to cooperate in investigations when those investigations involve professionals licensed by the two different boards.

Reports of Serious Adverse Drug Experiences: The draft MOU also states that the boards should investigate reports of serious adverse drug experiences involving compounded products. The MOU does not, however, impose a requirement for what PhRMA believes is a necessary next step – the establishment of a system to report to FDA the receipt of reports of serious adverse drug experiences. When the state agency learns of a serious adverse drug experience potentially associated with a

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compounded product, the agency should, by regulation, be required to report that information to FDA.

PhRMA notes that the draft MOU does require the state agency to report to FDA any "deaths, serious illnesses, and potential serious health hazards related to the interstate distribution of a drug product compounded in [State]." page 15. However, the draft MOU appears to contemplate that this reporting will be done after the state's investigation and may not include a report to FDA's Medwatch program or other adverse drug experience reporting system. Thus, the possibility exists that FDA or a drug manufacturer would receive a timely report of an adverse drug experience from a health care provider, i.e., a hospital or emergency treatment provider, who is not aware that the patient received a compounded drug. To avoid any possible misunderstanding about the source of an adverse drug experience, PhRMA urges FDA to modify the MOU to require that states establish, by regulation, a procedure for reporting promptly to FDA any reported adverse drug experience associated with use of a compounded drug.

Compounding in Violation of the Food, Drug, and Cosmetic Act (FDCA): The draft MOU sets forth the bases on which a pharmacist or physician compounding drug products may violate the FDAMA exemption from the federal Food, Drug, and Cosmetic Act and therefore represent the marketing of a new drug without a valid new drug application. Because the inclusion of this information will assure that each state agency is clear about the bases for violation of the federal law, PhRMA urges FDA to continue to include this information in the MOU.

Maintenance of Records of Investigations of Complaints: The draft MOU states that the state agency will maintain records of complaints, investigations of complaints, and responses to complainants for three years, but does not specify a starting date for the running of the three years. PhRMA recommends that, in the interest of clarity and the Agency's ability to verify that complaints have been investigated and resolved, the MOU specify that the state agency will maintain the records for three years from the date that the complaint is finally resolved.

Definition of Inordinate Amounts of Compounded Drugs: The draft MOU states that the dispensing or distribution of compounded drugs equal to or greater than 20 percent of the total number of prescriptions dispensed or distributed, constitutes the dispensing or distribution of an inordinate amount of compounded drugs, which puts the pharmacy in violation of the FDCA. In addition, the draft MOU states that the dispensing or distribution of a compounded drug product, including various strengths of

the same active ingredient, that constitutes more than 5 percent of the total number of prescriptions dispensed or distributed by that pharmacy constitutes the dispensing or distribution of an inordinate amount of compounded product, in violation of the FDCA. PhRMA recommends that FDA establish this amount in the final MOU but monitor the practice of shipping compounded products across state lines to determine whether the percentage figure needs to be decreased.

PhRMA would be happy to provide additional information on any of these issues.

Sincerely,

Marjorie E. Powell